

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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GAIL FIALKOV, *on behalf of himself and all
others similarly situated*,

Plaintiff,

-against-

ALCOBRA LTD., YARON DANIELY, and
DALIA MEGIDDO,

Defendants.
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GEORGE B. DANIELS, United States District Judge:

**MEMORANDUM DECISION AND
ORDER**

14 Civ. 09906 (GBD)

Plaintiffs bring this purported class action on behalf of all persons who purchased Alcobra Ltd. (“Alcobra”) common stock between July 14, 2014 and October 22, 2014 (the “Class Period”). (*See* Am. Compl. ¶ 13, ECF No. 33.) Plaintiffs bring claims against corporate Defendant Alcobra and individual Defendants Yaron Daniely and Dalia Megiddo under section 10(b) of the Securities Exchange Act (the “Exchange Act”) and Rule 10b-5 promulgated thereunder. (Am. Compl. ¶¶ 123–26.) Plaintiffs also bring claims under section 20(a) of the Exchange Act against individual Defendants Yaron Daniely and Dalia Megiddo. (Am. Compl. ¶¶ 127–32.)

Defendants move to dismiss the Amended Class Action Complaint pursuant to Rules 12(b)(2) and 12(b)(6) of the Federal Rules of Civil Procedure.

I. BACKGROUND

Alcobra is an Israeli pharmaceutical company focused on the development of the drug candidate metadoxine (“MDX”) for the treatment of adult attention-deficit/hyperactivity disorder (“ADHD”). (Am. Compl. ¶¶ 1, 3, 20.) Daniely was Alcobra’s CEO and director of the

company's board of directors during the Class Period. (Am. Compl. ¶ 21.) Megiddo co-founded Alcobra and served as a director on Alcobra's board of directors from February 2008 through August 2014. (Am. Compl. ¶ 22.) During the class period, Megiddo owned or controlled about twenty percent of Alcobra's voting stock. (Am. Compl. ¶ 22.)

Before presenting a new drug to the Food and Drug Administration ("FDA") for approval, a company must successfully complete a three-phase clinical investigation. (Am. Compl. ¶¶ 31–32.) Phase I consists of a study with approximately twenty to eighty subjects whose purpose is to determine the safety of the drug and its most common side effects. (Am. Compl. ¶ 34.) *See* 21 C.F.R. § 312.21(a). The purpose of Phase II is to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study. 21 C.F.R. § 312.21(b). (*See* Am. Compl. ¶ 35.) Phase II studies usually involve a few dozen to three hundred patients. (Am. Compl. ¶ 35.) Phase III studies gather additional information about the drug's safety and effectiveness by testing it on a much larger group of subjects than in the prior phases. (Am. Compl. ¶ 36.) Phase III studies usually involve several hundred to several thousand subjects. (Am. Compl. ¶ 36.) 21 C.F.R. § 312.21(c).

The analysis of data from a clinical study based on the total number of patients who were initially assigned to receive either the active drug or a placebo is referred to as an intention-to-treat ("ITT") analysis. (Am. Compl. ¶ 39 (citing Sandeep K. Gupta, *Intention-to-treat concept: A Review*, Persp. in Clinical Res., July–Sept. 2011, at 109).) An analysis based on a subset of those patients is referred to as a modified ITT ("mITT") analysis. (Am. Compl. ¶ 42.)

Alcobra completed two Phase II studies in 2011 and 2013. (Am. Compl. ¶ 4.) The studies produced few reports of adverse events, and they indicated the effectiveness of MDX was statistically significant among study participants with predominantly inattentive ADHD. (Am.

Compl. ¶ 4.) Based on these two Phase II studies, Alcobra proceeded to a Phase III study. (Am. Compl. ¶ 5.) Alcobra relied on a clinical research organization to conduct the Phase III study. (Am. Compl. ¶ 61.) Plaintiffs argue that Defendants' false and misleading statements about the Phase III study give rise to this suit. (Pls.' Opp'n to Defs.' Mot. to Dismiss ("Opp'n") at 4, ECF No. 40.)

In July 2014, Alcobra and Daniely made a number of statements indicating that the Phase III study's enrollment had been completed. (*See* Am. Compl. ¶¶ 59, 63, 65.) A July 14, 2014 Alcobra press release quoted Daniely as saying: "I would like to thank all the patients who participated in the trial, as well as the professional work by our investigators who quickly and rigorously enrolled patients in less than four months." (Am. Compl. ¶ 59.) The following day, at an investor forum, Daniely stated that Alcobra had "announced the completion of enrollment in our first adult Phase III study." (Am. Compl. ¶ 63.) Daniely also said at the investor forum that "there has never been in history a positive Phase II ADHD study that did not lead to a positive Phase III. There have been multiple Phase 2 failures, many of them public, but if you go back 15 years there has never been a positive Phase II in ADHD that was not followed by a positive Phase III. And it's a very strong statement, I realize, but it's the fact." (Am. Compl. ¶ 63.) At an August 11, 2014 investor conference call, Daniely, when speaking of the Phase III study enrollment, said: "We congratulate our investigators for their rapid and meticulous job and thank all patients who participated in the trial." (Am. Compl. ¶ 68.)

In an interview published on September 25, 2014 in *Globes*, a Hebrew-language Israeli newspaper, Megiddo responded to a question about Alcobra's Phase III study by answering: "Alcobra will succeed. I should say—I sleep very well at night. We performed the stage II trial, and the present one is identical. We saw the results, so I'm not worried. I don't believe in

anxiety, I believe in numbers.” (Am. Compl. ¶ 70; *see* Apton Decl., Ex. F, *Globes* Interview of Dalia Megiddo dated September 25, 2014 (“Megiddo Interview”), ECF No. 41-6.) When the interview was published, Megiddo was a significant shareholder but no longer served as a director on Alcobra’s board. (*See* Am. Compl. ¶ 22.)

On October 6, 2014, Alcobra announced the disappointing results of the Phase III study, and Alcobra’s stock price declined markedly that day. (*See* Am. Compl. ¶¶ 72–75, 118.) Alcobra issued a press release and held a conference call announcing that “[i]n a [mITT] population . . . , MDX demonstrated a statistically significant improvement in ADHD symptoms compared to placebo The mITT population was derived by a post hoc exclusion of four subjects with extreme placebo responses” (Am. Compl. ¶¶ 72–73.) At least one article published that day characterized the Phase III study as a failure. (*See* Am. Compl. ¶ 75 (citing Adam Feuerstein, “Alcobra ADHD Drug Fails Key Study Except When Patients Removed From Analysis,” *TheStreet* (Oct. 6, 2014), <http://www.thestreet.com/story/12902857/1/alcobra-adhd-drug-fails-key-study-except-when-patients-removed-from-analysis.html>).) On Friday, October 3, 2014—the last full trading day before the release of the October 6, 2014 press release—Alcobra stock closed at \$14.11 per share. (Am. Compl. ¶ 118.) On Monday, October 6, 2014, Alcobra stock closed at \$6.12 per share. (Am. Compl. ¶ 118.) The Amended Complaint alleges that the October 6 announcement amounted only to a partial corrective disclosure of the results of the Phase III study, and the true results were revealed on October 22 and 23, 2014. (Am. Compl. ¶ 77–78.)

On October 22, 2014, Lenard Adler, a member of Alcobra’s board of advisers, presented at the annual meeting of the American Academy of Child and Adolescent Psychiatry (“AACAP”). (Am. Compl. ¶ 79.) In his presentation, Adler described the results of the Phase III

MDX study. (Am. Compl. ¶ 80.) Adler also presented the results of a new mITT and another post hoc analysis of the Phase III results. (Am. Compl. ¶¶ 80–83.) The following day, Alcobra issued a press release summarizing Adler’s presentation. (Am. Compl. ¶ 85.) The press release stated that a new mITT analysis conducted by Alcobra excluded “only 2 patients, both from the placebo treatment group” (Am. Compl. ¶ 87.) The press release explained that the mITT excluding two patients differed from Alcobra’s previously-released mITT: “Importantly, this analysis is different from the post-hoc modified ITT analysis which the company reported on previously as part of the top-line release. The previous analysis excluded 4 patients from the ITT after identifying extreme placebo responses using a combination of statistical and clinical justifications” (Am. Compl. ¶ 87.) The press release also summarized the results of a “new post-hoc analysis . . . evaluat[ing] the outcome of exclusion of entry criteria violators (i.e., patients who failed to meet major inclusion/exclusion criteria).” (Am. Compl. ¶ 88.) That “analysis, performed by a blinded expert, identified 8 patients (5 from the placebo group and 3 from the MDX group) who were excluded from the ITT analysis for [sic] a cohort of 289 subjects.” (Am. Compl. ¶ 88.)

The press release stated that a post-hoc analysis combining these two modifications of the ITT population—removing “the 2 subjects excluded based on the pre-specified analysis and the 8 subjects excluded based on the post-hoc entry criteria violation analysis”—indicated that MDX demonstrated an advantage over placebo. (Am. Compl. ¶ 88.)

On Wednesday, October 22, 2014, Alcobra stock closed at \$5.68 per share. (Am. Compl. ¶ 119.) Alcobra’s stock price declined to \$4.20 per share on Thursday, October 23, 2014, \$3.63 per share on Friday, October 24, 2014, and \$3.53 per share on Monday, October 27, 2014. (Am. Compl. ¶ 119.)

II. LEGAL STANDARDS

A. Motion to Dismiss Under Rule 12(b)(6)

“A Rule 12(b)(6) motion challenges the legal sufficiency of the claims asserted in a complaint.” *Trs. of Upstate N.Y. Eng’rs Pension Fund v. Ivy Asset Mgmt.*, No. 13 Civ. 03180, 2015 WL 5472944, at *13 (S.D.N.Y. Sept. 16, 2015). In deciding a Rule 12(b)(6) motion, a court “accept[s] all factual allegations in the complaint as true . . . and draw[s] all reasonable inferences” in favor of the plaintiffs. *Holmes v. Grubman*, 568 F.3d 329, 335 (2d Cir. 2009) (quoting *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d 122, 124 (2d Cir. 2008)). A court is “not, however, ‘bound to accept conclusory allegations or legal conclusions masquerading as factual conclusions.’” *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (quoting *Rolon v. Henneman*, 517 F.3d 140, 149 (2d Cir. 2008)). In order to survive such a motion, a complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A court deciding a Rule 12(b)(6) motion is not limited to the face of the complaint. A court “may [also] consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit.” *ATSI Commc’ns v. Shaar Fund. Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

B. Liability Under Section 10(b) and Rule 10b-5

“For a violation of Section 10(b) and Rule 10b-5, a plaintiff must plead a plausible claim that includes the action’s basic elements: (1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance . . . ; (5) economic loss; and (6) loss causation[.]” *Kleinman v. Elan Corp.*, 706 F.3d 145, 152 (2d Cir. 2013) (alterations in original) (internal citations and quotation marks omitted). In addition, a securities fraud complaint must meet the heightened pleading standards of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (“PSLRA”). *Id.* Rule 9(b) requires that the “circumstances constituting fraud” must be “state[d] with particularity.” Fed. R. Civ. P. 9(b). Under the PSLRA, the pleaded facts must give “rise to a strong inference” of fraudulent intent. 15 U.S.C. § 78u-4(b)(2)(A). A complaint must identify untrue statements specifically and, if applicable, it must identify the omitted facts that are “necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading.” *Id.* § 78u-4(b)(1); *Kleinman*, 706 F.3d at 152. “[T]he reason or reasons why the statement is misleading” must also be pleaded. 15 U.S.C. § 78u-4(b). “To prove liability against a corporation . . . a plaintiff must prove that an agent of the corporation committed a culpable act with the requisite scienter, and that the act (and accompanying mental state) are attributable to the corporation.” *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 195 (2d Cir. 2008).

C. Control Person Liability Under Section 20(a)

Section 20(a) establishes secondary liability for “[e]very person who, directly or indirectly, controls any person” directly liable under the Exchange Act. 15 U.S.C. § 78t(a); *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 371 n.6 (2d Cir. 2014). “To establish a *prima facie* case

of control person liability, a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI Commc'ns, Inc.*, 493 F.3d at 108.

III. PLAINTIFFS' ALLEGATIONS FAIL TO STATE A CLAIM

A. Falsity

Plaintiffs have failed to plead any false or misleading statements by Defendants. In the securities fraud context, a false or incomplete statement alone is not actionable. *See In re Keryx Biopharm., Inc. Sec. Litig.*, No. 13 Civ. 1307, 2014 WL 585658, at *7 (S.D.N.Y. Feb. 14, 2014). "[T]here must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Dalberth v. Xerox Corp.*, 766 F.3d 172, 183 (2d Cir. 2014) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)). "[I]t bears emphasis that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information." *Kleinman*, 706 F.3d at 152 (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011)). "Disclosure is required . . . only when necessary 'to make statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* at 153 (alteration in original) (quoting *Matrixx*, 563 U.S. at 44). The Second Circuit has found that words such as "encouraging," when used in connection with the results of a drug trial, do not generally give rise to liability under the securities laws. *Kleinman*, 706 F.3d at 153; *see In re Keryx*, 2014 WL 585658, at *7.

Plaintiffs purport to identify three sets of false statements: (1) Alcobra's announcements in July and August 2014 that it had completed patient enrollment for the Phase III study (Am.

Compl. ¶¶ 59, 63, 65, 68); (2) purported “guarantees of success” made by Daniely at a July 15, 2014 investor forum and by Megiddo in a September 25, 2014 newspaper interview (Am. Compl. ¶¶ 63, 70); and (3) statements made by Daniely and Alcobra about the exclusion of four participants from the first mITT (Am. Compl. ¶¶ 73–74.). (See Opp’n at 8.)

1. Patient Enrollment Statements

Plaintiffs argue that the statements regarding the completion of patient enrollment for the Phase III study were materially false because “while patient enrollment was in fact completed, it was not completed properly.” (Opp’n at 9.) Plaintiffs argue that the fact that a post hoc analysis indicated that eight patients violated enrollment criteria shows that the enrollment had not been completed in the manner that Daniely had described it—“rigorously” and “meticulous[ly].” (Opp’n at 9 (citing (Am. Compl. ¶¶ 59, 68.).)

Statements thanking investigators for conducting patient enrollment “rigorously” and in a “meticulous” manner constitute mere puffery—i.e., “exaggerated general statements that make no specific claims on which [reasonable persons] could rely.” *Pelman v. McDonald’s Corp.*, 237 F. Supp. 2d 512, 528 n.14 (S.D.N.Y. 2003). Additionally, the eight enrollment criteria violators did not have a material effect on the results of the Phase III study. The ITT analysis, which included all eight enrollment criteria violators, found that MDX was not statistically effective in terms of treatment for ADHD. (See Am. Compl. ¶ 118.) And the mITT analysis excluding all eight criteria violators also found that the effectiveness of MDX was not statistically significant. (See Am. Compl. ¶ 88.) Plaintiffs do not allege that Defendants’ statements about the completion of patient enrollment for the Phase III study indicated that Phase III study would succeed. MDX was only found to demonstrate an advantage over placebo after two additional

subjects were excluded from the analysis. (*See* Am. Compl. ¶ 88.) Plaintiffs have failed to plead falsity with regard to the patient enrollment statements.

2. Purported “Guarantees of Success”

Plaintiffs identify two statements purportedly guaranteeing the success of the Phase III study. (Opp’n at 12.) First, they point to a statement Daniely made at a July 15, 2014 investor forum discussing the history of Phase II ADHD studies. (Am. Compl. ¶ 63.) Second, Plaintiffs cite to an interview Megiddo gave to an Israeli newspaper in which she spoke about the Phase III study. (Am. Compl. ¶ 70.)

At the July 15, 2014 investor forum, Daniely said that “there has never been in history a positive Phase II ADHD study that did not lead to a positive Phase III And it’s a very strong statement, I realize, but it’s the fact.” (Am. Compl. ¶ 63.) Plaintiffs acknowledge that this statements is not false “in and of itself.” (Sept. 22, 2015 Oral Arg. Tr. at 58, ECF No. 45.) Plaintiffs argue that the statement’s suggestion that the Phase III study would succeed because the Phase II studies had succeeded was false because Alcobra had been less careful in conducting the Phase III study than it had been in conducting the Phase II study, as evidenced by the finding of eight entry criteria violators. (Sept. 22, 2015 Oral Arg. Tr. at 57–58, ECF No. 45.)

A reasonable investor could not rely on this statement about the performance of other drugs in the past to conclude that the MDX Phase III was guaranteed to be a success. Moreover, even if Plaintiffs are right that Alcobra exercised less care in conducting the Phase III trial than it had in conducting the Phase II trial, the eight entry criteria violations did not affect the outcome of the

Phase III trial. Plaintiffs have failed to plead that Daniely's statements at the July 15, 2014 investor forum were materially false or misleading.

In the September 25, 2014 interview in *Globes*, a Hebrew-language Israeli newspaper, Megiddo responded to a question about Alcobra's Phase III study by answering: "Alcobra will succeed. I should say—I sleep very well at night. We performed the stage II trial, and the present one is identical. We saw the results, so I'm not worried." (Am. Compl. ¶ 70.)

At the time that she made those statements, Megiddo no longer served on Alcobra's board. (See Am. Compl. ¶ 22 (alleging that Megiddo served on Alcobra's board through August 2014).)¹ Megiddo's status as a minority shareholder also does not render her Alcobra's agent; an agency relationship requires evidence that the principal controls the agent. *In re Glob. Crossing, Ltd. Sec. Litig.*, No. 02 Civ. 00910, 2005 WL 1907005, at *9 (S.D.N.Y. Aug. 8, 2005). The Amended Complaint therefore fails to adequately allege that Megiddo spoke on behalf of Alcobra.² *Id.*

¹ The *Globes* article is contradictory about Megiddo's affiliation with Alcobra. The article appears to state both that Megiddo served as an Alcobra director at the time that the article was published and that she was no longer involved with Alcobra. (Cf. Megiddo Interview at 5 ("In Alcobra, where [Megiddo] serves as a director . . ."), with Megiddo Interview at 7 ("Today, Megiddo . . . is not involved in Alcobra.")) Plaintiffs, however, do not dispute that Megiddo was not a director at the time of the interview. (See Am. Compl. ¶ 22; Opp'n at 16–17.)

² Defendants argue that this Court lacks personal jurisdiction over Megiddo because she is an Israeli citizen residing in Israel, and Plaintiffs have failed to allege that she has sufficient contacts with the United States. "The plaintiff bears the burden of establishing that the court has jurisdiction over the defendant when served with a Rule 12(b)(2) motion to dismiss." *Whitaker v. Am. Telecasting, Inc.*, 261 F.3d 196, 208 (2d Cir. 2001) (citing *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 507 (2d Cir.1994)). At the pleading stage, a "plaintiff may carry this burden by pleading in good faith . . . legally sufficient allegations of jurisdiction, i.e., by making a prima facie showing of jurisdiction." *Id.* (alteration in original) (internal quotation marks omitted). An individual's status as a shareholder is alone insufficient to establish personal jurisdiction over that individual. See, e.g., *Alki Partners, L.P. v. Vatas Holding GmbH*, 769 F. Supp. 2d 478, 490 (S.D.N.Y. 2011) (holding that allegations that individuals were principal and sole shareholders of corporations were alone insufficient to establish personal jurisdiction over

Plaintiffs also fail to plead that Megiddo's statements were false or misleading. Plaintiffs argue that Megiddo's statements indicate that Alcobra had disclosed the results of the Phase III study to Megiddo, and Megiddo then misrepresented those results in the interview. (*See* Opp's at 13–14.) The Amended Complaint, however, does not allege that Alcobra disclosed the results of the Phase III study to Megiddo before those results were announced publicly. Megiddo's comments were merely statements of opinion, that is, "expectations for the future rather than presently existing, objective facts." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 531 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi* (2d Cir. Mar. 4, 2016). Such statements are "actionable only if the defendant's opinions were both false and not honestly believed when they were made." *Id.* (quoting *Kleinman*, 706 F.3d at 153) (internal quotation marks omitted). Plaintiffs do not sufficiently allege that Megiddo did not honestly believe that the Phase III study would succeed.

3. Statements About Exclusion of Four Participants From Phase III mITT

Plaintiffs argue that Alcobra's statements, made on October 6, 2014, that the first Phase III mITT excluded four study participants under the so-called "three standard deviation rule" were false because a subsequent mITT excluded only two participants under that rule. (Opp'n at 18.) The "three standard deviation rule" is "a statistical rule that identifies outliers by finding values that are different by more than three standard deviations from the mean of the group." (*See* Am. Compl. ¶ 74 (quoting Daniely's comments at October 6, 2014 conference call).)

The Amended Complaint's extensive quotations from Daniely's statements during an October 6, 2014 conference call show, however, that the first Phase III mITT excluded subjects

those individuals), *aff'd sub nom. Alki Partners, L.P. v. Windhorst*, 472 F. App'x 7 (2d Cir. 2012). Plaintiffs' allegations are insufficient to make a prime facie showing of jurisdiction over Megiddo.

under *both* the “three standard deviation rule” *and* a “post hoc exclusion” of patients who experienced a forty percent or greater decline on a clinical measure of ADHD symptoms. (*See* Am. Compl. ¶ 74.) In disclosing the subsequent mITT, Alcobra explained: “Importantly, this analysis is different from the post-hoc modified ITT analysis which the company reported on previously as part of the top-line release. The previous analysis excluded 4 patients from the ITT after identifying extreme placebo responses using a *combination* of statistical *and clinical* justifications, as described previously.” (*See* Am. Compl. ¶ 106 (emphasis added).) In other words, the Amended Complaint itself shows that the first mITT used an exclusion criteria to omit patients from the ITT population that the subsequent mITT did not employ.

“When the plaintiff’s allegation is refuted by the document on which it relies, it cannot be considered plausible.” *City of Roseville Emps.’ Ret. Sys. v. EnergySolutions, Inc.*, 814 F. Supp. 2d 395, 425 (S.D.N.Y. 2011) (citing *Koncelik v. Savient Pharm., Inc.*, No. 08 Civ. 10262, 2010 WL 3910307, at *5 (S.D.N.Y. Sept. 29, 2010)). Plaintiffs have failed to plead that Alcobra’s statements regarding its first mITT were false or misleading.

B. Scienter

Plaintiffs have failed to plead scienter. The PSLRA requires a plaintiff to “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A). “The plaintiff may satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness.” *ATSI Commc’ns, Inc.*, 493 F.3d at 99 (citing *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 168–69 (2d Cir. 2000)). “[S]ecurities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants’ knowledge of facts or access to

information contradicting their public statements.” *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001) (quoting *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000)). “[I]n determining whether the pleaded facts give rise to a ‘strong’ inference of scienter, the court must take into account plausible opposing inferences.” *Id.*

A complaint fails to plead scienter under a theory of motive and opportunity if it does not allege that defendants possess unique motives not shared by virtually all corporate insiders. *Novak*, 216 F.3d at 307. Motives shared by virtually all corporate insiders include the desire to sustain “the appearance of corporate profitability” or the “success of an investment.” *Id.* (quoting *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 268 (2d Cir. 1996)). Instead, plaintiffs must allege that “defendants benefitted in some concrete and personal way from the purported fraud.” *Id.* at 307–08.

The Amended Complaint does not allege that Daniely or Megiddo sold any shares during the Class Period. Plaintiffs do not allege that Defendants had any unique motives to commit fraud. Plaintiffs’ central scienter argument is that “MDX was Alcobra’s sole drug candidate, [and] FDA-approval of the drug was absolutely essential to the Company’s success.” (Opp’n at 21 (citing Am. Compl. ¶¶ 91–95).) Plaintiffs seek to make out a sufficient allegation of scienter on the basis of the “core operations doctrine.” (Opp’n at 21.) Under that doctrine, “the fact that [adequately alleged false or misleading] statements concerned the core operations of the company supports the inference that the defendant knew or should have known the statements were false when made.” *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004). The Second Circuit has not ruled on the viability of the core operations doctrine following the 1995 passage of the PSLRA. *In re China Mobile Games & Entm’t Grp., Ltd Sec. Litig.*, No. 14 Civ. 04471, 2016 WL 922711, at *9 n.11 (S.D.N.Y. Mar. 7,

2016) (citing *Plumbers & Pipefitters Local Union No. 630 Pension-Annuity Trust Fund v. Arbitron Inc.*, 741 F. Supp. 2d 474, 490 (S.D.N.Y. 2010)). The majority of courts in the Second Circuit have found that “the ‘core operations’ doctrine may provide support for but not an independent basis of scienter.” *Lipow v. Net1 UEPS Techs., Inc.*, No. 13 Civ. 09100, 2015 WL 5459730, at *24 n.11 (S.D.N.Y. Sept. 16, 2015). Plaintiffs’ scienter allegations do not extend beyond the core operations doctrine. “The desire to have a drug application approved . . . can be ascribed to any pharmaceutical company.” *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 570 (S.D.N.Y. 2011). That motive is insufficiently concrete to infer scienter. *Id.*

Plaintiffs do not satisfy the scienter requirement by alleging facts showing strong circumstantial evidence of conscious misbehavior or recklessness. Plaintiffs have not adequately alleged that either Daniely or Megiddo had knowledge or access to information contradicting their statements about the Phase III study. Consequently, Plaintiffs have failed to plead scienter on any plausible theory.

C. Control Person Liability for Individual Defendants

As Plaintiffs have failed to plead a primary violation, they cannot establish control person liability. *See ATSI Commc’ns, Inc.*, 493 F.3d at 108. Plaintiffs’ claims under section 20(a) of the Exchange Act are DISMISSED.


IV. CONCLUSION

Defendants' Motion to Dismiss the Amended Complaint is GRANTED.

The Clerk of Court is directed to close the motion at ECF No. 34.

Dated: March 30, 2016
New York, New York

SO ORDERED.



GEORGE B. DANIELS
United States District Judge